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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,644	01/08/2002	Jacques F. Banchemau	112917-143	7691
28089	7590	08/23/2005	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP			CHANDRA, GYAN	
399 PARK AVENUE			ART UNIT	
NEW YORK, NY 10022			PAPER NUMBER	
			1646	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/042,644

Applicant(s)

BANCHEREAU ET AL.

Examiner

Gyan Chandra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/2/2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 53- 68, 78-79 is/are pending in the application.
- 4a) Of the above claim(s) 1-52, 69-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53- 68, 78-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/6/02, 1/3/03, 8/1/05, 12/30/02
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group V, claims 53-68, and species (xv) psoriasis and (xxvi) an antibody as the interferon antagonist in the reply filed on 6/02/2005 is acknowledged. The traversal is on the ground(s) that Group V and I are drawn to treating an autoimmune disease using interferon antagonist alone and interferon antagonist in combination with Flt3 ligand and that searching the Inventions of Groups V and I together would not impose a serious search burden. This is not found persuasive because Group V requires searches for treating autoimmune diseases using interferon antagonist whereas searches for Group I requires searching database, e.g., NPL for all Flt3L ligands i.e., that binds Flt3, an antagonist or agonist in combination with any interferon antagonist. This would impose undue burden on the Examiner. Further, searches for treating an autoimmune disease comprising an interferon antagonist (Group V) and the searches for treating an autoimmune disease comprising an interferon antagonist and an Flt3 ligand are not coextensive.

Applicant traverses that they are entitled to further examination of species if the genus claim is allowable. As stated in the previous office action mailed on 4/28/2005, upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

The requirement is still deemed proper and is therefore made FINAL.

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### **Status of Application, Amendments, And/Or Claims**

Claims 1-52 and 69-77 are withdrawn as being non elected invention. The addition of new claims 78-79 has been made of record.

Claims 53- 68, and 78-79 are pending and are examined on the merit to the extent that they read on the elected species (xv) psoriasis and (xxvi) an antibody as the interferon antagonist.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Priority***

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant claims priority to the Provisional Application US 60/260541 filed on Jan 9, 2001, which does not provide support for the instantly claimed invention. Therefore, the priority of the instant application is the instant filing date of 1/8/2002.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53-68 and 78-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Benoit et al (IDS, US Patent No. 5,919,453, July 6, 1999).

Claims are drawn to a method of treating an autoimmune disease in a subject comprising administering an effective amount of an interferon antagonist to treat the disease wherein antagonist comprises an anti-interferon  $\alpha$  antibody or an antigen binding fragment and the autoimmune disease is psoriasis.

Benoit et al teach that interferon  $\alpha$  is a potent immunoregulatory molecule and is associated with a number of autoimmune diseases and inflammatory disorders including systemic lupus erythematosus (SLE), type I diabetes, psoriasis, rheumatoid arthritis, Behcet's disease, multiple sclerosis, acquired immunodeficiency syndrome (AIDS) and many more (column 1, lines 55-67). They state that administration of interferon  $\alpha$  exacerbate underlying disease in a patient with psoriasis and multiple sclerosis and induces SLE like syndrome (column 2, lines 5-9). Further, they describe using antibody against interferon type I (IFN  $\alpha/\beta$ ) as an antagonist against the biological activities of human IFN  $\alpha$  (column 2, lines 18-20 and lines 46-54). They teach using antibodies to inhibit or to neutralize the effect of interferon  $\alpha$ ,  $\beta$ ,  $\omega$  sub species. They

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describe pharmaceutical composition comprising effective doses of antibodies to treat psoriasis (column 6, lines 8-15).

Claims 53-68 and 78-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Skurkovich et al (IDS, US Patent No. 5888,511, March 30, 1999).

Claims are drawn to a method of treating an autoimmune disease in a subject comprising administering an effective amount of an interferon antagonist to treat the disease wherein antagonist comprises an anti-interferon  $\alpha$  antibody or an antigen binding fragment and the autoimmune disease is psoriasis.

Skurkovich et al teach that autoimmune diseases are caused by disturbance of synthesis of interferons and other substances as tumor necrosis factor (TNF) and production of autoantibodies to target cells, such as CD4 cells, which damages patient's immune system (column 1, lines 11-20). They teach using antibodies against (i) interferon  $\alpha$ , (ii) interferon  $\alpha$  receptor, (iii) interferon  $\gamma$  and (iv) interferon  $\gamma$  receptor, to treat autoimmune diseases including AIDS (column 4, lines 34-67 through column 6, lines 1-3). They describe treating patients with autoimmune diseases such as SLE, rheumatoid arthritis, diabetes type I (examples 3 – 7).

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra  
AU 1646  
15 August 2005

  
**JANET L. ANDRES**  
**SUPERVISORY PATENT EXAMINER**